

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**CITY OF WARWICK RETIREMENT
SYSTEM**, *individually and on behalf of all
others similarly situated*,

Plaintiff,

v.

CATALENT, INC., *et al.*,

Defendants.

Civil Action No. 23-1108 (ZNQ) (JTQ)

OPINION

QURAISHI, District Judge

THIS MATTER comes before the Court upon a Motion to Dismiss (the “Motion,” ECF No. 58) filed by Defendants Catalent, Inc. (“Catalent”), John Chiminski, Alessandro Maselli, and Thomas Castellano (collectively, “Defendants”). Defendants filed a brief in support of the Motion (“Moving Br.,” ECF No. 58-1). Plaintiff City of Warwick Retirement System, individually and on behalf of all others similarly situated, plus Court-appointed Lead Plaintiffs Public Employees’ Retirement System of Mississippi and SEB Investment Management AB, (collectively, “Plaintiffs”), filed an opposition (“Opp’n Br.,” ECF No. 66), to which Defendants replied (“Reply Br.,” ECF No. 67). After careful consideration of the parties’ submissions, the Court decides the Motion without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1.¹ For the reasons outlined below, the Court will **GRANT IN PART and DENY IN PART** Defendants’ Motion to Dismiss.

¹ Hereinafter, all references to “Rule” or “Rules” refer to the Federal Rules of Civil Procedure.

I. BACKGROUND AND PROCEDURAL HISTORY²

Defendant Catalent is an outsourced drug manufacturer for pharmaceutical and biotech companies. (Am. Compl., ECF No. 47 ¶¶ 2, 35.) In early 2020, Catalent’s revenue hit record highs because of the COVID-19 pandemic, which sparked an increase in demand for vaccine products. (*Id.* ¶ 2.) However, by mid-2021, demand for vaccine products had decreased significantly because a large number of people had already received the COVID-19 vaccine, leaving Catalent with excess production capacity, excess employees, and an increase in quality control issues which were costly to remediate. (*Id.* ¶ 3.) Plaintiffs allege that Defendants engaged in a multi-faceted accounting scheme in order to artificially inflate Catalent’s revenue and mislead investors into thinking that the company was generating sustainable revenue growth from August 30, 2021 to May 7, 2023 (the “Class Period”). (*Id.* ¶¶ 1, 4.) Plaintiffs allege that Defendants made three categories of fraudulently misleading statements and omissions during the Class Period: (1) those concerning Catalent’s quality control issues and procedures (the “Quality Control Statements”); (2) those concerning Catalent’s compliance with the Generally Accepted Accounting Principles (the “GAAP Compliance Statements”); and (3) those concerning the general demand for non-vaccine products (the “Non-Vaccine Demand Statements”). (*Id.* ¶¶ 5–16.)

Plaintiffs filed their class action Complaint against Defendants on February 24, 2023. (ECF No. 1.) On September 15, 2023, Plaintiffs filed the operative Amended Complaint, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act (“Exchange Act”) (Counts I and II, respectively).³ (ECF No. 47.) The Amended Complaint includes information that Plaintiffs gathered from thirteen confidential witnesses, who are former Catalent employees and others with

² For the purpose of considering the instant Motion, the Court accepts all factual allegations in the Complaint as true. *See Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

³ Count I alleges a violation of both Section 10(b) and corresponding Rule 10b-5 of the Exchange Act.

knowledge (“Confidential Witnesses”). (*Id.* ¶¶ 114–266.) On November 15, 2023, Defendants filed the instant Motion to Dismiss. (ECF No. 58.)

II. JURISDICTION

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act, 15 U.S.C. § 78aa.

III. LEGAL STANDARDS

A. Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) “requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (abrogated on other grounds)).

A district court conducts a three-part analysis when considering a motion to dismiss pursuant to Rule 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). “First, the court must ‘tak[e] note of the elements a plaintiff must plead to state a claim.’” *Id.* (alteration in original) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must accept as true all of the plaintiff’s well-pleaded factual allegations and “construe the complaint in the light most favorable to the plaintiff.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). The court, however, may ignore legal conclusions or factually unsupported accusations that merely state the defendant unlawfully harmed me. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether “the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). A facially plausible claim “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 210 (quoting

Iqbal, 556 U.S. at 663). On a Rule 12(b)(6) motion, the “defendant bears the burden of showing that no claim has been presented.” *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

B. Rule 9

Under Rule 9(b) and in conjunction with Rule 12(b)(6), fraud-based claims are subject to a heightened pleading standard, requiring a plaintiff to “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). A court may grant a motion to dismiss a fraud-based claim if the plaintiff fails to plead with the required particularity. *See Frederico v. Home Depot*, 507 F.3d 188, 200–02 (3d Cir. 2007). The level of particularity required is sufficient details to put the defendant “on notice of the precise misconduct with which [it is] charged.” *Id.* at 201 (quoting *Lum v. Bank of Am.*, 261 F.3d 217, 223–24 (3d Cir. 2004) (abrogated on other grounds)) (internal quotation marks omitted). At a minimum, Rule 9(b) requires a plaintiff to allege the “essential factual background that would accompany the first paragraph of any newspaper story—that is, the ‘who, what, when, where and how’ of the events at issue.” *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir. 2006). The heightened pleading standard set forth in Rule 9(b) applies to fraud claims brought under the Exchange Act. *See, e.g., In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006).

C. The PSLRA

In addition to Rule 9(b)’s heightened pleading requirements, Congress enacted the Private Securities Litigation Reform Act (“PSLRA”), 15 U.S.C § 78u, *et seq.*, to require an even higher pleading standard for plaintiffs bringing private securities fraud actions. *In re Suprema*, 438 F.3d at 276. This heightened pleading standard is targeted at preventing abusive securities litigation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (“Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial

costs on companies and individuals whose conduct conforms to the law.”); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006) (identifying “ways in which the class-action device was being used to injure the entire U.S. economy” and listing examples such as “nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests, and manipulation by class action lawyers of the clients whom they purportedly represent”) (internal quotation marks omitted).

The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss. *Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). First, under 15 U.S.C. § 78u-4(b)(1), the complaint must “specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity.” *Id.* (quoting *Winer Family Tr. v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007)) (internal quotation marks omitted). Second, the complaint must, “with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” *Id.* (quoting 15 U.S.C. § 78u-4(b)(2)) (internal quotation marks omitted).

Both provisions of the PSLRA require facts to be pled with “particularity.” *Id.* at 253. This particularity language echoes the requirements of Rule 9. *Id.*; see Fed. R. Civ. P. 9(b) (“[A] party must state with particularity the circumstances constituting fraud or mistake.”). Indeed, although the PSLRA replaces Rule 9(b) as the pleading standard governing private securities class actions, Rule 9(b)’s particularity requirement “is comparable to and effectively subsumed by” PSLRA § 78u-4(b)(1). *Id.* (discussing the PSLRA’s requirement that a plaintiff plead the “who, what, when, where and how: the first paragraph of any newspaper story”) (internal quotation marks omitted).

IV. DISCUSSION

A. Violation of Exchange Act Section 10(b) (Count I)

Count I of the Complaint alleges a violation of Section 10(b) of the Exchange Act and Rule 10b-5 of the regulations promulgated by the SEC under the Act. The private right of action under Section 10(b) and Rule 10b-5 “creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997). To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege: “(1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation.” *Gold v. Ford Motor Co.*, 577 F. App’x 120, 122 (3d Cir. 2014) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005)). In relevant part, Rule 10b-5 makes it unlawful for an individual “[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security.” 17 C.F.R. § 240.10b-5(b).

Here, the Motion to Dismiss only challenges the sufficiency of Plaintiffs’ allegations pertaining to the three elements of material misrepresentation or omission, scienter, and loss causation. The Court will address each disputed element in turn.

1. Material Misrepresentation or Omission

Defendants argue that Count I should be dismissed because the Amended Complaint fails to identify any actionable, materially false statements. They contend the Quality Control Statements, GAAP Compliance Statements, and Non-Vaccine Statements constitute mere puffery,

opinions,⁴ beliefs that Defendants held, and forward-looking projections. (Moving Br. at 14–21.) These opinions should not be considered actionable unless Plaintiffs also plead specific facts to show that the speaker knew the opinions were false, which they fail to do here. (*Id.* at 15–17, 19–20.) Additionally, Defendants argue that their vague, forward-looking Non-Vaccine Demand Statements are immunized by the PSLRA’s “safe harbor.” (*Id.* at 19–20; Reply Br. at 5.)

Plaintiffs maintain that Defendants committed both material misrepresentations and omissions in their public statements during the Class Period regarding quality control, GAAP compliance, and non-vaccine demand issues despite having a duty to do so. (Opp’n Br. at 1–2.) Specifically, Plaintiffs argue that Defendants either misrepresented or failed to disclose pervasive internal quality control weaknesses at Catalent, accounting improprieties, overstated earnings and revenue, artificially low inventory reserves, and declining demand for non-vaccine products, as corroborated by the Confidential Witness accounts.⁵ (*Id.* at 3–10, 12–13, 16–19.) Plaintiffs maintain that Defendants had an affirmative duty to disclose information they withheld because it was material to other information that Defendants chose to disclose, thereby putting the subject matter “in play,” for example, Form 483s issued by the FDA.⁶ (*Id.* at 13–15, 20.) Plaintiffs urge the Court to reject Defendants’ argument that all of the statements were mere inactionable opinions, because opinions are actionable if, as is the case here, known material information undermining the given belief was omitted from the disclosure or the speaker lacked a reasonable basis for the opinion. (*Id.* at 15–16, 18–20.) Moreover, Plaintiffs argue that the Non-Vaccine Demand

⁴ Regarding the Quality Control Statements, Defendants additionally argue that they are not materially misleading. (Moving Br. at 16–17.)

⁵ Plaintiffs insist that the Confidential Witness accounts are reliable and should be credited, as they have independent value and are also corroborated by the Form 483s. (Opp’n Br. at 26–27.) Furthermore, Plaintiffs contend that the truth regarding these issues was revealed in a series of partial disclosures which Catalent released only after the issues had occurred, resulting in a “cratered” stock price. (*Id.* at 11.)

⁶ As the Complaint notes, a “Form 483” is the notice issued by FDA to company management when it has observed what it believes to be a violation of a statute or regulation within its purview. (Am. Compl. at 4 n.7.)

Statements and Quality Control Statements are not mere puffery as Defendants contend, because they, respectively, concern concrete information about the performance of specific products⁷ and are not “so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality.”⁸ (*Id.* at 14–15, 20.)

Generally, information is material if it would be important to a reasonable investor in making investment decisions. *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000). An omitted fact is material if there is a substantial likelihood that a reasonable investor would have viewed its disclosure as “having significantly altered the total mix of information available to that investor.” *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992) (internal quotation marks omitted). A duty to disclose an omitted material fact arises only when disclosure would be necessary to make the statement “not misleading” in “light of the circumstances under which they were made.” *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014) (internal quotation marks omitted). Because materiality is a mixed question of law and fact, it is appropriate for a district court to dismiss allegations of misrepresentations or omissions as inactionable as a matter of law “[o]nly if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality.” *Shapiro*, 964 F.2d at 280 n.11.

The Court will consider the materiality of the alleged misrepresentations and omissions made across each of the three disclosure categories, and whether they are actionable.

⁷ Plaintiffs specify that the Non-Vaccine Demand Statements concern not simply forward-looking beliefs, but a mix of present and future statements that are rooted in a discussion of Catalent’s then-current Biologics pipeline. For this reason, Plaintiffs argue that the PSLRA’s safe harbor provision does not apply. (*Id.* at 20–21.) Even if the statements could be considered forward-looking, the provision still does not apply, Plaintiffs argue, because Defendants failed to provide meaningful cautionary language to accompany the statements. (*Id.* at 21.)

⁸ To the contrary, Plaintiffs insist that the omitted quality control issues are material, as evidenced by the subsequent decline of Catalent’s stock price once the quality control issues were later revealed. (Opp’n Br. at 15.)

a. Quality Control Statements

As an initial matter, the Court finds that several Quality Control Statements, identified in the following paragraphs of the Amended Complaint,⁹ amount to no more than immaterial puffery: portions of the Company's 2021 10-K statement (paragraphs 270, 271), , , the Management Discussion and Analysis statement from the Company's 10-Q statements for the first three quarters of 2022 and the first two quarters of 2023 (paragraphs 293, 314, 338, 392, 427, respectively). On their face, these statements are "more general statements regarding [Catalent's] values and motivations," as well as merely optimistic statements about the future of the company's business. *Hall v. Johnson & Johnson*, Civ. No. 18-1833, 2019 WL 7207491, at *15 (D.N.J. Dec. 27, 2019); *see also Shapiro*, 964 F.2d at 280 n.11. The Court therefore finds that they are "not determinable, verifiable statements. They are the types of vague statements upon which reasonable investors do not rely." *In re Hertz Glob. Holdings, Inc. Sec. Litig.*, Civ. No. 13-7050, 2017 WL 1536223, at *10–11 (D.N.J. Apr. 27, 2017), *aff'd*, *In re Hertz Glob. Holdings*, 905 F.3d 106 (3d Cir. 2018). Accordingly, the Court finds that the above-referenced Quality Control Statements are not actionable.

A few of the Quality Control Statements in the Company's 2021 and 2022 10-K statements, cited in the Amended Complaint at paragraphs 272, 273 (the first sentence), and 363 (in two separate sentences), differ to some degree because they assert that Catalent operates its business "in accordance with" current good manufacturing practices ("CGMP").¹⁰ These statements are more than mere puffery, insofar as they make "determinable, verifiable" claims of compliance with CGMP and are more specific than vaguely optimistic hopes for the future of the business. *In re*

⁹ Throughout this section of the Opinion, when referencing Statements located in specific paragraphs of the Amended Complaint, the Court refers only to the bold, italicized Statements therein unless otherwise specified.

¹⁰ The Court adopts Plaintiffs' acronym "CGMP" because that is how it is pled in the Amended Complaint. More commonly referred to as "cGMP," these are the regulations for quality control and safety that are promulgated and enforced by the FDA. (Am. Compl. ¶ 6.)

Hertz, 2017 WL 1536223, at *10–11. Plaintiffs allege these were false or misleading given the series of Form 483s that FDA issued when it inspected Defendants’ facilities. (Am. Compl. ¶¶275–276, 364.) As Defendants correctly note, however, the Amended Complaint glosses over the fact that the Company also acknowledged that it received “inspectional observations,” i.e., Form 483s, and was working to resolve them:

In addition, our facilities are subject to periodic inspection by the FDA, the DEA, and other equivalent local, state, and foreign regulatory authorities as well as our customers. ***All FDA, DEA, and other regulatory inspectional observations have been resolved or are on track to be completed at the prescribed timeframe provided in commitments to the applicable agency in all material respects.***

(Moving Br. at 16) (quoting Am. Compl. at ¶ 274.) Under the circumstances the Company’s “we comply” statements cannot be considered misleading. Therefore, the Court finds that the Quality Control Statements discussing CGMP compliance are not actionable.¹¹

Next, the Court will address Quality Control Statements that constitute opinions, located in Amended Complaint paragraphs: 274 (last sentence only), 363 (select sentences only, *see infra*), and 327 (all statements therein except the first statement). An opinion is considered misleading, and thus is actionable, under Section 10(b) of the Exchange Act and Rule 10b-5 if it: “(i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language.” *City of Warren Police & Fire Retirement Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 684–86 (3d Cir. 2023) (interpreting *Omnicare, Inc. v. Labs. Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175 (2015)). In other words, opinions may still be actionable “if they do not reflect the speaker’s subjective belief or if they omit known material information undermining that belief.” *Roofer’s Pension Fund v. Papa*, Civ. No. 16-2805, 2018 WL 3601229, at *10 (D.N.J. July 27, 2018).

¹¹ The Court does not reach Defendants’ separate argument that a Form 483 is merely “interim FDA feedback,” rather than an actual finding of noncompliance. (Moving Br. at 16.)

As an initial matter, there are no allegations in the Amended Complaint that Defendants did not sincerely and subjectively believe their opinions were true, (*see generally* Am. Compl.); Plaintiffs appear to concede this point because they only argue and allege that Defendants lacked a reasonable basis for their opinions.¹² (*See* Opp’n Br. at 15–16.) The Court will thus examine only whether each of Defendants’ opinions had a reasonable basis.

The opinion in paragraph 274, from Catalent’s 2021 Form 10-K, reads: “We believe that our operations are in compliance in all material respects with the regulations under which our facilities are governed.” This statement was made on August 30, 2021. (*See* ECF No. 59, Ex. 1.) The Amended Complaint only alleges violations of various regulations—namely GAAP, CGMP, and ASC 606 violations¹³—that seemingly took place before that date. For instance, Catalent did not receive any Form 483s until October 2021, two months after the 2021 Form 10-K was filed. (Am. Compl. ¶ 63.) Moreover, the GAAP and related ASC 606 violations detailed in paragraphs 215 to 229 rely on Confidential Witness 2, who did not work for Catalent until June 2022. (*Id.* ¶ 117.) Corroborating this timeline is the chart in paragraph 83, which shows a spike in inventory that only started in June of 2022.¹⁴ (*Id.* ¶ 83.) Based on this timing of events as alleged, the Court does not find that Defendants lacked a reasonable basis for stating this opinion in August 2021; thus, it is not actionable.

The opinions in paragraph 363, from Catalent’s 2022 Form 10-K, read: (1) “We believe our quality and regulatory track record to be a favorable competitive differentiator”; and (2) “We

¹² The Court adds that Plaintiffs’ reliance on *In re PTC Therapeutics, Inc. Sec. Litig.*, Civ. No. 16-1124, 2017 WL 3705801, at *17 (D.N.J. Aug. 28, 2017) is unavailing, because that case at that pincite discusses scienter rather than the materiality element of opinions.

¹³ There are various allegations in the Amended Complaint that Catalent violated its own internal Standard Operating Procedures (“SOPs”), however, such violations are irrelevant to this opinion, which contemplates only violations of regulations. (*See* Am. Compl. ¶ 274.)

¹⁴ Understated and deliberately accumulated inventory are some of Plaintiffs’ GAAP violation allegations. (Am. Compl. ¶ 279.)

believe that our sites and equipment are in good condition, are well maintained, and are able to operate at or above present levels for the foreseeable future, in all material respects.”

The reasonableness of the first opinion, which discusses Defendants’ belief about a previous track record it has held as a business, is not refuted by any of the allegations in the Amended Complaint. This statement was made in August 2022, and it is unclear what period of time prior to that the referenced “regulatory track record” was meant to encompass; Catalent could have been opining on its track record for the past one, three, ten, or twenty years. The Class Period at issue started only one year prior. Accordingly, the Court finds that Catalent’s first opinion here about its prior track regulatory record, about some unspecified prior point in time, was not unreasonable when made and thus is not actionable.

The Court finds that the second opinion, however, which was also made in August 2022, does not have a reasonable basis in light of the details alleged in the Amended Complaint and thus is actionable. (*See* Am. Compl. ¶¶ 132–37 (SOP violations, deviations from sanitation rules, and contamination in Bloomington facility buildings, including food and blood particulates in vials, both before and during August 2022); *id.* ¶¶ 157, 159 (contamination in Brussels facility both before and during Summer 2022)¹⁵; *see also id.* ¶ 214 (ruined batches of product because of quality control issues in Bloomington facility more noticeable to Confidential Witness 10 in second half of 2022).)¹⁶

The opinions in paragraph 327, which were made by Defendant Maselli during Catalent’s 2022 Q3 Earnings Call in May 2022, read in bold:

[W]e are pleased with the progress and incredible work done by our teams in addressing the [Form] 483 as we stated in previous calls. 483 need CAPAs by definition. And some of those CAPAs

¹⁵ Confidential Witness 7 worked at the Brussels facility from Summer 2021 to Summer 2022. (Am. Compl. ¶ 122.)

¹⁶ Confidential Witness 10 worked at the Bloomington facility from before the Class Period to the calendar end of Q4 2022. (Am. Compl. ¶ 125.)

require the facility to be paused in terms of manufacturing because they are more invasive and require engineering changes and some others don't.

So I would say that our progress in terms of addressing those requiring engineering changes and manufacturing pause have progressed well. As described in our prepared remarks, we are -- we have restarted manufacturing operations, which is good, especially for patients. But at the other end, we continue to work diligently on all our CAPA plan on that.

(Am. Compl. ¶ 327.) The opinions concern the aftermath of Catalent's receipt of a Form 483 in October 2021 at the Brussels facility, including the company's recovery therefrom leading up to the date the statement was made, May 3, 2022. (*Id.*; *see also* ¶¶ 68, 74, 78 (other Form 483s received during the Class Period were all later than May 2022).) Although the allegations in paragraphs 132 to 137, 157, 159, and 214 detail ongoing quality control issues until at least the Summer of 2022 across all three of Catalent's main locations, this opinion expresses satisfaction with the company's *progress* in improving quality control since the Form 483 was received in October of 2021, and the Court finds that the allegations do not articulate how the opinion on such progress lacked a reasonable basis. Indeed, the October 2021 Form 483 "highlighted CGMP issues with Novo Nordisk's Wegovy production by Catalent"—none of the allegations referenced herein (or by Plaintiffs in support of this opinion, *see id.* ¶ 328) suggest there was a lack of progress regarding those particular production issues. Accordingly, the Court finds that these opinions are not actionable.

Separately, the Quality Control Statement in Amended Complaint paragraph 435 is neither puffery nor an opinion. Rather, the Court considers it a forward-looking statement discussing the company's expectations. It refers to productivity issues and expected decreased revenue for Catalent's Q3 2023 from the company's Harmans/BWI facility: "None of these issues is expected to adversely impact the quality or commercial launch quantities of any product made at BWI in

light of, among other things, the level of ‘bright stock’ on hand.” (Am. Compl. ¶ 435.) There is no allegation that contradicts this future prediction, which on its face is not an affirmative misrepresentation (or misleading statement that omits a material fact). It is a mere explanation of the company’s present prediction for future business. As such, the Court finds that this Quality Control Statement is not actionable.

Additionally, there are a few additional Quality Control Statements which are neither opinions nor puffery, nor forward-looking statements; rather, they are assertions which the Court will consider in turn.

Paragraph 301 cites the following statement from Defendant Maselli during Catalent’s 2022 Q2 Earnings Call: “[W]e have not experienced any slowdown in our commercial activity or any impact there [in Brussels]. And in fact, I can confirm that the demand and the requests for Catalent’s services is as high as ever been” (Am. Compl. ¶ 301.) On that same call, Defendant Castellano then added a second assertion: “We said from the start that this was not a material financial contributor or impact for the company.” (*Id.*) The Earnings Call, held in February 2022, was to discuss Catalent’s financial results for the end of its fiscal second quarter of 2022, and these particular statements were made in reference to the aftermath of the Form 483 that the Brussels location received in October 2021. (*Id.*) Plaintiffs argue that these statements downplay the effects of the shutdown at Brussels that followed the Form 483 from January to March 2022, during which time that facility generated “zero commercial revenue” for Catalent. (Opp’n Br. at 14, 29; Am. Compl. ¶ 160.) Plaintiffs argue that Defendants instead “touted the substantial progress of the facility’s remediation efforts” through those statements. (Opp’n Br. at 14.) The Court agrees with Plaintiffs. By discussing commercial activity at the Brussels location, including customer requests for services, Defendants put that specific issue “in play,” entitling investors to know that, in fact, Brussels experienced “zero commercial revenue” after its shutdown, contrary to what Defendants

portrayed on the Earnings Call. *Roofer's Pension Fund*, 2018 WL 3601229, at *13–14 (agreeing with the plaintiffs that statements were actionable because the defendants “described the integration in entirely positive terms . . . while omitting known extensive problems that brought key integration processes to a halt”); *see also Shapiro*, 964 F.2d at 280 n.11. Accordingly, the Court finds that the statements are actionable because disclosure of this other material information which was omitted would have “significantly altered the mix of information available to a reasonable investor.” *Roofer's Pension Fund*, 2018 WL 3601229, at *14; *Shapiro*, 964 F.2d at 280 n.11.

Paragraph 327 from Catalent's 2022 Q3 Earnings Call states, cites another statement in bold that Plaintiffs:

Defendants Maselli and Castellano also commented on the regulatory remediation at Catalent's Brussel's facility with Defendant Castellano confirming that, “the Brussels remediation efforts are absolutely the bulk of the margin compression that we saw in comparison to the prior year levels.” Notwithstanding, Defendant Maselli boasted that remediation of the issues identified in the Form 483 was progressing well: **“Also in Europe, our drug product facility in Brussels continues to make substantial progress, which has allowed us to begin the restart of manufacturing operations at the site while we continue in parallel to enhance our overall site operations.”**

(Am. Compl. ¶ 327.) While at first glance this statement also appears actionable for the reasons stated immediately above, the Court finds that Defendants this time did not omit material information—to the contrary, before making this statement on the 2022 Q3 Earnings Call, Defendants acknowledged that the aftermath of the Brussels shutdown resulted in “the bulk of the margin compression” that Catalent experienced. (*Id.*) Therefore, although this statement, too, puts the specific issue of the remediation efforts of the Brussels location “in play,” no material facts were omitted with this disclosure that would have “significantly altered the mix of information

available to a reasonable investor.” *Shapiro*, 964 F.2d at 280 n.11. Therefore, the statement is not actionable.

Lastly, the Court finds that the sole remaining Quality Control Statement to be addressed, located in the last paragraph of Amended Complaint paragraph 363, is not actionable because it is simply not misleading. Rather, it is a warning to investors that Catalent’s “[f]ailure to comply with existing and future regulatory requirements . . . could adversely affect [its] results of operations and financial condition or results in claims from customers,” and that changes to Catalent’s procedures, including in response to the COVID-19 pandemic, “may increase [Catalent’s] costs or reduce [its] productivity and thereby affect [its] business, financial condition, or results of operations.” (Am. Compl. ¶ 363.) If anything, Catalent is being transparent with investors through this admission, not concealing material information or affirmatively disclosing misleading information.

In sum, the Court finds that only two Quality Control Statements are material and thus actionable. The first is the 2022 10-K statement insofar as it asserted that “[w]e believe that our sites and equipment are in good condition, are well maintained, and are able to operate at or above present levels for the foreseeable future, in all material respects.” (Am. Compl. ¶ 363.). The second statement is the earnings call on February 1, 2022 regarding Q2 2022 financial result, during which the following statements were made:

[W]e have not experienced any slowdown in our commercial activity or any impact there. And in fact, I can confirm that the demand and the requests for Catalent’s services is as high as ever been . . .

and

We said from the start that this was not a material financial contributor or impact for the company.

(Am. Compl. ¶ 301.) The Court finds the remainder of the Quality Control Statements are not actionable.

b. GAAP Compliance Statements

“Where statements about GAAP compliance are concerned, courts have deemed them to be opinions.” *In re Hertz*, 2017 WL 1536223, at *11; *Roofers’ Pension Fund*, 2018 WL 3601229, at *10. So too, here, the Court considers the GAAP Compliance Statements to be opinions, because GAAP standards are subjective and involve a wide range of acceptable procedures. *In re Ikon Office Solutions, Inc.*, 277 F.3d 658, 675 n.22 (3d Cir. 2002); *In re Hertz*, 2017 WL 1536223, at *11. As with the Quality Control Statements that are opinions, there are no allegations in the Amended Complaint that Defendants did not sincerely and subjectively believe their opinions were true, (*see generally* Am. Compl.); Plaintiffs again appear to concede this point by only arguing that the opinions are actionable because they omit material information that was known to Defendants which undermined the opinions. (*See* Opp’n Br. at 18.) The Court will thus examine only whether Defendants’ opinions omitted material, undermining information.

There are three subcategories of GAAP Compliance Statements; the Court will address each one in turn.

First, there are the Statements that claim Catalent’s disclosures comply with other sections of the Securities Exchange Act, and that “[t]he information contained in the [disclosures] fairly presents, in all material respects, the financial condition and results of operations of the Company.” They are located in Amended Complaint paragraphs 278, 291, 312, 336, 361, 390, and 425. Plaintiffs claim that these Statements are materially false and misleading because they fail to disclose several adverse material facts, including that Catalent materially overstated its revenue in violation of the GAAP, had material weakness in internal control over financial reporting related

to revenue recognition, and materially understated its inventory reserves for excess, unsaleable, and expiring inventory in violation of the GAAP. (Am. Compl. ¶ 279.) The Court agrees. Elsewhere in the Amended Complaint, but absent from Defendants’ disclosures, is information suggesting that Catalent employees were pushed and pressured by management to increase production to an excessive level, even against the express wishes of clients, in order to meet revenue forecasts. (*Id.* ¶¶ 146, 174–83, 207–11, 213.) These pressures resulted in issues concerning some of Catalent’s customers that the Court finds material and adverse to these disclosures, including that Catalent had to send invoices late—sometimes upwards of two years late—because production was delayed due to quality control issues; batches of product had to be discarded because of quality issues; customers were billed for ruined batches of product; and some customers requested to reduce their purchases from Catalent or even cancel their business altogether. (*Id.* ¶¶ 201–02, 208, 214.) These opinions are therefore actionable, as they omit “known material information undermining [Defendants’] beliefs,” as relayed herein. *Roofers’ Pension Fund v. Papa*, Civ. No. 16-2805, 2018 WL 3601229, at *10 (D.N.J. July 27, 2018).

Second, the Amended Complaint cites Defendants’ various Statements about Catalent’s inventory reserves. The Statements in paragraphs 329, 354, and 419 refer to Catalent’s decision to increase inventory levels at the onset of COVID-19 as a “strategic decision,” and the Statements in paragraphs 286, 330, and 360 represent that Catalent’s inventory levels were thereafter kept at appropriate levels. (Am. Compl. ¶¶ 329, 354, 419.) The Court cannot find any allegations that undermine Defendant’s representation that increasing its inventory levels was a “strategic decision” by the company, putting aside the fact that nearly all of these Statements were made prior to the bulk of the purportedly undermining allegations.¹⁷ (*See id.* ¶¶ 174–241 (discussing

¹⁷ A majority of the allegations Plaintiffs emphasize in their briefing were sourced from Confidential Witnesses 1 and 2, who did not work for Catalent until Summer 2022. (Am. Compl. ¶¶ 116–17.)

excessive inventory and issues tracking inventory, as well as purported accounting improprieties, but not Defendants’ intention behind increasing inventory), 179–81.) Therefore, the GAAP Compliance Statements in paragraphs 329, 354, and 419 are not actionable. After a careful review of the rest of Defendants’ Statements regarding inventory levels, the Court finds that only part of paragraph 360 is actionable. The Statement in paragraph 360, from Catalent’s 2022 Form 10-K, reads:

During fiscal 2022, we did not identify any significant risk, delay, or concern that had a substantial effect on such delivery, in part because of our adoption of various procedures to minimize and manage supply disruptions to our ongoing operations, including through business continuity plans and careful attention to inventory levels to assure supply of needed inputs. Our existing procedures, which are consistent with cGMP and other regulatory standards, are intended to assure the integrity of our supply against any contamination.

(Am. Compl. ¶ 360.) The last sentence, for the same reasons stated *supra* regarding CGMP compliance, is not actionable. However, the Court finds that the other Statement in paragraph 360 is actionable, because the Amended Complaint elsewhere alleges—but Catalent did not disclose—that Catalent did face concerns about its delivery of products and services to customers; specifically, that one client, Sarepta therapeutics, specifically directed Catalent to stop manufacturing its products but Catalent did not listen, and Catalent additionally kept manufacturing more products for another client, AveXis, against its wishes in order to meet revenue goals. (*Id.* ¶¶ 209–10.) Such information undermines Catalent’s claims of paying “careful attention to inventory levels” and that there was “no significant . . . concern” regarding inventory levels during Catalent’s fiscal year 2022. Accordingly, the Court finds that the Statement is actionable. *Roofer’s Pension Fund v. Papa*, Civ. No. 16-2805, 2018 WL 3601229, at *10 (D.N.J. July 27, 2018).

Third, Statements in Amended Complaint paragraphs 277, 288 to 290, 309 to 311, 333 to 335, 359, and 387 to 389 represented that Catalent’s management made all estimates, assumptions, and necessary adjustments in accordance with GAAP when preparing Catalent’s various financial statements, and ensured that the company’s financial reporting was “effective.” The Court finds that these Statements are not actionable, because they simply detail the procedures that Catalent has in place regarding financial reporting, (Am. Compl. ¶ 277, 290), and explain to investors how the company prepares its financial statements, including with sometimes–necessary management input. Even so, there are no allegations that undermine Catalent’s representation that it did generally prepare its various financial statements “in accordance with” the GAAP principles, (*see, e.g., id.* ¶ 288). Moreover, when a representation is more specific, it is accompanied by qualifying language so that investors understand the basis for Catalent’s conclusions. (*See id.* ¶ 277 (“*Based on this assessment, our management concluded that our internal control over financial reporting was effective as of June 30, 2021.*” (emphasis added))); *see In re Cognizant Tech. Solutions Corp. Sec. Litig.*, Civ. No. 16-6509, 2018 WL 3772675, at *25 (D.N.J. Aug. 8, 2018) (finding statement not actionable that was “preceded with a qualifier”). As such, these GAAP Compliance Statements are not actionable.

In sum, the following GAAP Compliance Statements are material and thus actionable: the Statements in Amended Complaint paragraphs 278, 291, 312, 336, 361, 390, and 425, and the first Statement in paragraph 360. The Court finds the remainder of the GAAP Compliance Statements are not actionable.

c. Non-Vaccine Demand Statements

As an initial matter, the Court finds that several Non-Vaccine Demand Statements identified in the following paragraphs of the Amended Complaint, amount to no more than

immaterial puffery: 303, 322 (except for the first sentence), and 343. (*See* Am. Compl. ¶¶ 303, 322, 343.) These statements are “more general statements regarding [Catalent’s] values and motivations,” as well as merely optimistic statements about the future of the company’s business. *Hall v. Johnson & Johnson*, Civ. No. 18-1833, 2019 WL 7207491, at *15 (D.N.J. Dec. 27, 2019); *see also Shapiro*, 964 F.2d at 280 n.11. The Court finds that they are “not determinable, verifiable statements. They are the types of vague statements upon which reasonable investors do not rely.” *In re Hertz*, 2017 WL 1536223, at *10–11. Accordingly, the Court finds that the above-referenced Non-Vaccine Demand Statements are not actionable.

There are several Non-Vaccine Demand Statements, located in Amended Complaint paragraphs 304 (Defendant Maselli’s first paragraph of statements only), 344, 350, 384, 399 (the first sentence only), and 415 to 417, that are too specific to constitute puffery but that are not opinions either. Rather, the Court considers them forward-looking statements that represent the company’s anticipated growth. (*See* Am. Compl. ¶¶ 304, 344, 350, 384, 399, 415–17.) There is no allegation that contradicts these future predictions, which are not affirmative misrepresentations (or misleading statements that omit material facts) in any event, but mere explanations of the company’s projections for growth at the time disclosed. As such, the Court finds that these Non-Vaccine Demand Statements are not actionable.¹⁸

Next, the Court will address the Non-Vaccine Demand Statements that constitute opinions. As with the two other categories of alleged misrepresentations, there are no allegations in the Amended Complaint regarding the Non-Vaccine Demand Statements that Defendants did not sincerely and subjectively believe their opinions were true, (*see generally* Am. Compl.); Plaintiffs again appear to concede this point by only arguing that Defendants lacked a reasonable basis for

¹⁸ Because of the Court’s findings, Defendants’ argument for safe harbor protection under the PSLRA for these forward-looking statements is moot. (*See* Moving Br. at 19; Opp’n Br. at 20.)

their opinions and failed to disclose material, undermining information. (*See* Opp’n Br. at 19.) The Court will thus examine only whether each of Defendants’ opinions had a reasonable basis and whether they contain material, undermining omissions.

The opinion in the first Statement of paragraph 322, stated by Defendant Chiminski during Catalent’s 2022 Q2 Earnings Call, reads: “Demand remained strong in [the Biologics] segment, including a notable increase from several of our large gene therapy customers for viral vector manufacturing.” (Am. Compl. ¶ 322.) There are no specific allegations in the Amended Complaint that undermine this opinion, or that suggest that Defendant Chiminski otherwise lacked a reasonable basis for this opinion based on happenings at Catalent during that time. The closest Plaintiffs come to convincing the Court otherwise are through allegations that contain broad statements about an expected “lull” in demand after COVID-19 across the company, references to slowed growth in mid-2021 following the COVID-19 pandemic, and a “massive exodus” of Catalent employees—which has nothing to do with *customer* behavior as portrayed in the Statement—in Fall 2022. (*Id.* ¶¶ 55, 306–07, 242.) These other allegations do not provide an unreasonable basis for the opinion in paragraph 322. The opinion is therefore not actionable in light of the Amended Complaint’s other allegations.

Plaintiffs attempt to support their claims against the opinions in paragraphs 324¹⁹ and 352²⁰ by pointing the Court to the same allegations of an expected post-COVID “lull” in demand, a slowdown in growth in mid-2021, and an exodus of Catalent employees. Just like with the opinion in paragraph 322, these allegations do not provide an unreasonable basis for the opinions in paragraphs 324 and 352, which discuss Catalent’s relationship with its clients and transition from

¹⁹ The opinion in paragraph 324, stated by Defendant Maselli during the 2022 Q3 Earnings Call, reads: “I will state that our relationship with our COVID partners, which has been built through the pandemic, has never been stronger, remains strong and long-lasting”

²⁰ The opinion in paragraph 352, stated by Defendant Maselli at the 2022 Q4 Earnings Call, emphasized that the company’s transition from vaccine-producing assets to non-vaccine products was “seamless.”

vaccine-producing assets to non-vaccine products, respectively. The Court finds that these opinions are therefore not actionable, as they are not undermined in any way by the other allegations in the Amended Complaint.

Plaintiffs also rely on these same insufficient allegations to attempt to support their claims against several alleged misrepresentations, found in the following paragraphs: 304–05, 321, 323, 345 (the second half), 351, and 352 (the last Statement only), 383, 399 (except for the first Statement), 410 to 411, and 414. These Statements discuss growth in demand for Catalent’s non-vaccine products, including through its Biologics sector. Defendants argue that “Plaintiffs do not allege demand was any different than Defendants represented.” (Moving Br. at 18.) The Court agrees, as it cannot find any allegations to refute the representations—specific and general alike—portrayed in the above-listed paragraphs of the Amended Complaint.²¹ Simply put, Defendants are correct that the Amended Complaint’s repeated reliance on a general understanding of a “lull” in demand after COVID-19 is detrimental to Plaintiff’s claims based on the Non-Vaccine Demand Statements, particularly in the absence of other allegations that would cause the Court to consider if Defendants’ assertions here did indeed affirmatively mislead investors or omit material information that would have “significantly altered the total mix of information available to that investor.” *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992). The Court therefore finds that these Non-Vaccine Demand Statements are not actionable.

²¹ With respect to the Statements in paragraphs 383, 399, 410 to 411, and 414, the Amended Complaint points the Court to an additional allegation to be considered alongside the allegations of the slowdown and “lull” in demand—paragraph 246, which illustrates one instance of a sales capacity opening up in Bloomfield that would not be filled in some time despite needing to be filled. This one allegation is not sufficient for the Court to find that material facts were omitted from Defendants’ Non-Vaccine Demand Statements, nor that the Statements are misleading, especially in light of the fact that the Statements discuss the demand with holistic measurements, such as in comparison to the company’s “overall funnel” of new opportunities, “long-term outlook” on growth, and its performance during several other previous fiscal quarters. (Am. Compl. ¶¶ 383, 399.) Moreover, there are still no allegations that challenge the specific percentages of growth illustrated by the Non-Vaccine Demand Statements. (*See id.* ¶¶ 399, 414.) Plaintiffs’ decision to highlight paragraph 246 thus does not change the Court’s conclusion, as the Court regardless considers the entire Amended Complaint in its analysis.

Lastly, the Court finds that the remaining Non-Vaccine Demand Statements to be addressed, located in Amended Complaint paragraphs 345 (the first statement only), 349, and 352 (the unresolved portions), and 400, are not actionable because they are simply not misleading. If anything, these Statements simply discuss the type of business Catalent is doing, *i.e.*, whether it is working with “large-scale commercial programs” and other “large players” looking to do business quickly, or not. The Court cannot find any allegations to suggest that these Statements are misleading, and Plaintiffs identify none. The Court therefore finds that they are not actionable.

In sum, the Court finds that none of the Non-Vaccine Demand Statements are actionable.

2. Scier

With respect to the requisite element of scier, Defendants contend that the Amended Complaint lacks specific allegations as to what Defendants actually knew or did.²² (Moving Br. at 3, 23–26 (characterizing Confidential Witness accounts as “vague and speculative”).) Instead, Plaintiffs put forth an inadequate “fraud by hindsight” theory by alleging that Defendants “must have known” of the alleged fraud by virtue of their employment with Catalent and “hands-on” approach to management. (*Id.* at 22–23.) Defendants argue that, at best, Plaintiffs allege corporate mismanagement rather than knowing fraud. (Reply Br. at 11.) Moreover, Defendants argue that any inference of scier raised by the allegations is outweighed by a non-culpable inference that Defendants were unaware of any information that rendered their statements false. The non-culpable inference is supported by the Complaint’s failure to allege Defendants’ possession or receipt of information undermining their statements or to allege that any of the Confidential Witness told Defendants that they were sacrificing quality or engaging in improper accounting practices in order to meet revenue targets. Likewise, there are no allegations that Defendants

²² In support of this point, Defendants add that none of the Confidential Witnesses worked directly with the Defendants; rather, they were multiple rungs lower on the reporting ladder. (*Id.* at 24.)

engaged in irregular stock sales or profited from the purported fraud. (*Id.* at 27–28 (emphasizing that non-culpable inferences outweigh culpable inferences).)

Plaintiffs argue that their allegations are sufficient because they show that Defendants were deeply involved in Catalent’s day-to-day business, including by attending Portfolio Reviews and other informative meetings regularly, and that Defendants had access to a dashboard that tracked both quality and financial data, as well as multiple other information sources about Catalent’s performance across various areas. (*Id.* at 6, 10, 22–23.) Moreover, Plaintiffs insist that the statements at issue concern “core matters of central importance” to Catalent’s business, and thus raise an inference of scienter, even without evidence of direct knowledge by an individual defendant,²³ when considered alongside the allegations concerning Defendants’ knowledge based on their positions in the company. (*Id.* at 23–24.) Specifically, Plaintiffs maintain that Biologics and its three key production facilities, which are described in detail in the Confidential Witness accounts, are central to Catalent’s core business. (*Id.* at 24.)

“Scienter” refers to the “mental state [of] intent to deceive, manipulate or defraud.” *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). Under the PSLRA’s pleading requirement, a plaintiff must “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” *Avaya*, 564 F.3d at 267 (quoting 15 U.S.C. § 78u–4(b)(2)) (internal quotation marks omitted). The scienter pleading standard requires a plaintiff to allege facts giving rise to a “strong inference of either reckless or conscious behavior.” *Id.* Courts must weigh the “plausible nonculpable explanations for the defendant’s conduct” against the “inferences favoring the plaintiff.” *Tellabs*, 551 U.S. at 310. A “strong inference” of scienter is one that is

²³ Because direct evidence is not required in this situation, Plaintiffs urge the Court to reject Defendants’ argument that a non-culpable inference is raised here—to the contrary, Plaintiffs maintain there is an inference of scienter. (*Id.* at 28–29.)

“cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Id.* at 314, 324 (“The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the ‘smoking-gun’ genre, or even the most plausible of competing inferences.” (internal quotation marks omitted)).

“[I]n determining whether the pleaded facts give rise to a ‘strong’ inference of scienter, the court must take into account plausible opposing inferences. . . . A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter at least as likely as any plausible opposing inference.” *Tellabs*, 551 U.S. at 323–29. Although courts “aggregate the allegations in the complaint to determine whether [they] create[] a strong inference of scienter, plaintiffs must create this inference with respect to each individual defendant in multiple defendant cases.” *Winer Family Tr. v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007).

Here, the Amended Complaint alleges that individual Defendants Chiminski, Maselli, and Castellano, in their roles over time as CEO and CFO of Catalent, “spoke frequently about how involved they were in all aspects of the Company’s business.” (Am. Compl. ¶ 478.) Plaintiffs’ allegations highlight Defendants’ “hands-on involvement,” which they touted with pride right at the start of the Class Period. (*See id.* ¶¶ 480–81.) Catalent disclosed in its 2021 10-K: “Our senior management team is actively involved in setting quality policies, standards, and internal position papers as well as managing internal and external quality performance.” (*Id.* ¶ 479; *see also id.* ¶ 482 (2022 10-Q stating that Catalent’s CEO and CFO participate with other management to “evaluate[] the effectiveness of the design and operation of [Catalent’s] disclosure controls and procedures”)) Defendant Chiminski himself has stated: “We’re constantly looking at the market. We’re constantly looking at what our customers’ needs are. And as a management team, working closely with our Board. We’re looking out in the future to understand what strategic investments that we need to make so that we will have the capacity necessary for our customers and their

pipelines”; “We have engagement at the highest levels of management working with our suppliers to ensure that we get the components that we need”; and “we’re in constant dialogue with our Board. Every Board meeting has some component of the strategic capacity needs and CapEx that we’ll need to follow on. So we’re in regular dialogue here” These allegations alone separate this case from others in which courts have found that scienter was inadequately pled. *See In re Hertz*, 2017 WL 1536223, at *23 (insufficient scienter based on only two allegations, tied to unknown corporate defendants—a sole purported admission in a Form 10-K that the company knew about certain material weaknesses, and “the existence of an inappropriate tone at the top” of the company); *Spar v. Celsion Corp.*, Civ. No. 20-15228, 2023 WL 2069725, at *7–8 (D.N.J. Feb. 6, 2023) (insufficient scienter based on: (1) an alleged departure from ordinary care by making statements which the defendants “did not affirmatively know the results of” and (2) shares sold by the defendants); *Lewakowski v. Aquestive Therapeutics, Inc.*, Civ. No. , 2023 WL 2496504, at *10-12 (insufficient scienter based on a “general corporate desire to retire debt and raise funds,” offerings of company stock, and a third allegation that the Court deemed a “blanket assertion[] of motive”).

The Amended Complaint additionally includes many specific allegations that the individual Defendants were made aware of certain situations at Catalent, beyond participating in quarterly Earnings Calls—for example, in September 2022 Defendant Castellano, the then-CFO, was “presented with the ‘brutal findings’ of an internal audit conducted at [the] Harmans [facility] which noted serious control issues requiring remediation, (Am. Compl. ¶¶ 13, 239–40); Defendant Chiminski visited the Bloomington facility “multiple times” and “on and off” during his employment, (*id.* ¶¶ 132, 143); Defendants Chiminski and Maselli spoke at a meeting with the Head of Global Supply Chain Biologics, at which “the details behind the contaminations and remediation efforts at Brussels were discussed,” (*id.* ¶ 165); Defendant Maselli visited the Harmans

facility for multiple weeks, for one full week at a time, as a member of a rotating executive team visitation strategy that lasted for six months (with just three other individuals taking turns visiting the site), (*id.* ¶ 212); and Defendant Maselli accessed company data “from his own smartphone” through the company dashboard, (*id.* ¶ 256).

Moreover, the Plaintiffs emphasize that Defendants had access to “comprehensive databases and other internal information channels.” (Opp’n Br. at 22.) The Amended Complaint alleges that Defendants had access to company information through Portfolio Review meetings, ELT meetings, the company’s XLT Dashboard which monitored various metrics, and TrackWise, a system which consolidated information regarding quality issues, inventory transactions, and revenue projections. (Am. Compl. ¶¶ 131–32, 243–44, 248–53.) Again, these allegations separate this case from others where scienter was not adequately pled. *See Spar*, 2023 WL 2069725, at *7–8 (“Defendants reiterate that Plaintiff cannot and does not allege that Defendants had access to the data at the time such statements were made.”).

The Court finds that these allegations, as corroborated by the Confidential Witness accounts,²⁴ are sufficient to raise a strong inference of at least reckless disregard on the part of the individual Defendants with respect to Catalent’s various issues as alleged in the Amended Complaint. *McCullough v. Advest, Inc.*, 754 F. App’x 109, 113 (3d Cir. 2018) (acknowledging access to information in finding that scienter adequately alleged). The Court therefore finds that the Amended Complaint adequately pleads the required scienter element.

²⁴ “[A] plaintiff in securities fraud actions can support a complaint by reliance on information attributed to confidential sources” but only “in two situations: (1) if the complaint sets forth other factual allegations, such as documentary evidence, which are sufficient alone to support a fraud allegation, or (2) when the confidential sources are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the confidential source would possess the information alleged.” *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 290 (D.N.J. 2007); *see also Nat’l Junior Baseball League v. Pharmanet Dev. Grp., Inc.*, 720 F. Supp. 2d 517, 538-39 (D.N.J. 2010). Here, the Court finds that the Confidential Witness accounts are described with sufficient particularity so as to support the probability that the Confidential Witnesses did possess the information alleged.

3. Loss Causation

Defendants separately argue that Plaintiffs fail to plead loss causation as a matter of law because the corrective disclosures referenced by the Amended Complaint do not suffice. (Moving Br. at 29.) Plaintiffs argue that they adequately allege loss causation because they need only show that the misrepresentation “touches upon” the reasons for the stock’s decline in value and the Amended Complaint meets that burden. (Opp’n Br. at 29.)

In the context of Rule 10b–5 claims, the Third Circuit applies the general causation principles of tort law to the element of loss causation. “[A]n allegation that the misrepresentations directly or proximately caused, or were a substantial contributing cause of, the damages sustained by plaintiff adequately [pleads] loss causation.” *EP Medsys., Inc. v. EchoCath, Inc.*, 235 F.3d 865, 884 (3d Cir. 2000) (internal quotation marks omitted); *see also* 15 U.S.C. § 78u–4(b)(4) (stating that in any private action arising under the PSLRA, “the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages”).

Here, the Amended Complaint alleges that a series of “partial disclosures” revealed the truth about Catalent’s operations, after which Catalent’s stock price dropped each time. (Am. Compl. ¶¶ 500–06.) The disclosures were comprised of both Catalent representations and media reports from third parties about Catalent’s conduct. For example, a *Washington Post* article dated September 20, 2022 revealed that the FDA had halted the release of millions of COVID-19 vaccine booster shots because of poor inspection, and had raised concerns about contamination, after which Catalent’s stock price declined by 9.3 percent. (*Id.* ¶ 500.) Catalent revealed other “operational challenges” across all three of its major facilities in a business update on April 14, 2023, after which its stock price declined by 26.8 percent. Courts in this district have held loss causation is adequately pled when a company’s stock price declines after media reports and disclosures

presented new information about the alleged fraud to the public. *See, e.g., In re Aurora Cannabis Inc. Sec. Litig.*, Civ. No. 19-20588, 2023 WL 5508831, at *5–7 (D.N.J. Aug. 24, 2023); *Hall*, 2019 WL 7207491, at *27–28. Accordingly, the Court finds that Plaintiffs adequately pled loss causation.

B. Violation of Exchange Act Section 20(a) (Count II)

Count II of the Complaint alleges a violation of Section 20(a) of the Exchange Act, a derivative claim. The only argument Defendants raise in support of dismissal of Count II is that because a primary violation of the securities laws (Count I) is not adequately pled, Count II must also be dismissed. The Court has already concluded that it will not dismiss Count I because Section 10(b) violations are adequately alleged for certain Quality Control Statements and GAAP Compliance Statements. Therefore, the Court will DENY Defendants’ Motion to Dismiss with respect to Count II as well.

IV. CONCLUSION

For the reasons stated above, the Court will **GRANT IN PART and DENY IN PART** Defendants’ Motion to Dismiss. The Motion will be **DENIED** as to Count I with respect to claims premised on the following alleged material misrepresentations:

- The Company’s 2022 10-K statement insofar as it asserted that “[w]e believe that our sites and equipment are in good condition, are well maintained, and are able to operate at or above present levels for the foreseeable future, in all material respects.” (Am. Compl. ¶ 363.);
- The Company’s earnings call on February 1, 2022 regarding Q2 2022 financial result, during which the actionable statements identified above were made (Am. Compl. ¶ 301);
- The Company’s 10-K statements for 2021 and 2022 and the 10-Q statements for Q1, Q2, and Q3 of 2022 and Q1 and Q2 statements of 2023 insofar as they included

certifications under Sarbanes-Oxley (Am. Compl. ¶¶ 278, 291, 312, 336, 361, 390.); and

- The Company's 10-K statement in 2022 insofar as it made assertions regarding the Company's assessment of risk with respect to its inventory levels. (Am. Compl. ¶ 360.)

The Motion will be **GRANTED** as to the remaining claims of Count I. These claims will be **DISMISSED** without prejudice. The Motion will be **DENIED** with respect to Count II. Plaintiffs will be given leave to file a Second Amended Complaint within 30 days to address the defects identified above. An appropriate Order will follow.

Date: **June 28, 2024**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE